



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,483	12/10/2001	David S. Soane	50225-8009.US09	7753
33603	7590	12/27/2004		
ACLARA BIOSCIENCES, INC. 1288 PEAR AVENUE MOUNTAIN VIEW, CA 94043				
EXAMINER NOGUEROLA, ALEXANDER STEPHAN				
ART UNIT			PAPER NUMBER	
1753				
DATE MAILED: 12/27/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,483

Applicant(s)

SOANE ET AL.

Examiner

ALEX NOGUEROLA

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 31-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/10/2001</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 31-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claims 31 and 39 contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 31 and 39 require “applying a voltage from a voltage source across each adjacent pair of electrodes such that the electrical field generated across the plurality of electrodes is larger than that achieved in applying a voltage from the voltage source across the electrodes positioned at each terminus of the main trench.” Applicants cite page 7, lines 21-26 and page 10, lines 1-3 as support for this limitation (table on page 6 of the preliminary amendment of April 22, 2004). However, these passages appear to disclose the opposite, that a substantially large voltage across the electrodes at the terminus of the main trench would be need to generate a similar electric field generated by applying a voltage across adjacent pairs of electrodes.

Art Unit: 1753

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 31-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 31 recites the limitation "each terminus" in line 5. There is insufficient antecedent basis for this limitation in the claim;

b) Claim 31, last paragraph: it is not clear if the method actually requires applying a voltage to the electrodes positioned at each terminus of the main trench;

c) Claim 31: as the voltage applied across the electrodes positioned at each terminus of the main trench can be arbitrarily set as large as desired, independent of the voltages across the plurality of adjacent pairs of electrodes, the last paragraph of claim 31 does not limit the voltage applied to the adjacent pairs of electrodes;

d) Claim 39 recites the limitation "each terminus" in line 6. There is insufficient antecedent basis for this limitation in the claim;

e) Claim 39, last paragraph: it is not clear if the method actually requires applying a voltage to the electrodes positioned at each terminus of the main trench; and

Art Unit: 1753

f) Claim 39: as the voltage applied across the electrodes positioned at each terminus of the main trench can be arbitrarily set as large as desired, independent of the voltages across the plurality of adjacent pairs of electrodes, the last paragraph of claim 31 does not limit the voltage applied to the adjacent pairs of electrodes.

Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 31, 35, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Pace (US 4,908,112) (“Pace”).

Addressing claim 31, Pace discloses a method for moving charged particles through a medium employing an electrical field (col. 3:52-65), the method comprising

providing a device comprising (a) a substrate having an upper surface (30), (b) a main trench (32) in the substrate extending downward from the upper surface (Figure 3), and (c) a

Art Unit: 1753

plurality of electrodes (12) positioned at intervals (Figures 1 and 2), including at each terminus (Figure 1), along the trench such as to be in electrical contact with a medium when present in the trench (Figure 3), the plurality of electrodes being connected to activate electrodes to provide an electrical field profile along the trench to move charged particles (implied by col. 9:20-36, which discloses a timing sequence for applying voltages to the electrodes);

placing a sample of the charged particles into the medium in the device (col. 9: 3-10); and

applying a voltage from a voltage source across each adjacent pair of electrodes

(col. 9:20-37) such that the electrical field generated across the plurality of electrodes is larger than that achieved in applying a voltage from the voltage source across the electrodes positioned at each terminus of the main trench (implied by “To achieve high resolution separation by molecular charge requires the application of intense electric field gradients, of the order of 250 volts/cm. Rather than apply a large voltage along the entire length of the conduit, much smaller voltages may be applied between more closely spaced but staggered electrodes 122 as seen in Fig. 4 and yet maintain high intensity fields.” *col. 9:20-26*)

Addressing claim 35, for the additional limitation of this claim see col. 5:35-44.

Addressing claim 38, for the additional limitation of this claim see col. 9:20-33.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1753

10. Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pace (US 4,908,112) ("Pace").

Addressing claim 36, Pace discloses a method for moving charged particles through a medium employing an electrical field (col. 3:52-65), the method comprising

providing a device comprising (a) a substrate having an upper surface (30), (b) a main trench (32) in the substrate extending downward from the upper surface (Figure 3), and (c) a plurality of electrodes (12) positioned at intervals (Figures 1 and 2), including at each terminus (Figure 1), along the trench such as to be in electrical contact with a medium when present in the trench (Figure 3), the plurality of electrodes being connected to activate electrodes to provide an electrical field profile along the trench to move charged particles (implied by col. 9:20-36, which discloses a timing sequence for applying voltages to the electrodes);

placing a sample of the charged particles into the medium in the device (col. 9: 3-10); and

applying a voltage from a voltage source across each adjacent pair of electrodes (col. 9:20-37) such that the electrical field generated across the plurality of electrodes is larger than that achieved in applying a voltage from the voltage source across the electrodes positioned at each terminus of the main trench (implied by "To achieve high resolution separation by molecular charge requires the application of intense electric field gradients, of the order of 250 volts/cm. Rather than apply a large voltage along the entire length of the conduit, much smaller voltages may be applied between more closely spaced but staggered electrodes 122 as seen in Fig. 4 and yet maintain high intensity fields." col. 9:20-26).

Pace does not mention particular intervals for the electrodes. However, Pace does disclose channel dimensions less than 100 microns (col. 5:35-44 and col. 5:60-66) and that the

Art Unit: 1753

electrodes should be closely spaced to achieve an intense electric field gradient (col. 9:20-22). In light of this disclosure, barring a contrary showing, to have the intervals between the electrodes in the claimed range is just a matter of optimizing the location of the electrodes for the desired field gradient.

Addressing claim 37, Pace discloses a method for moving charged particles through a medium employing an electrical field (col. 3:52-65), the method comprising

providing a device comprising (a) a substrate having an upper surface (30), (b) a main trench (32) in the substrate extending downward from the upper surface (Figure 3), and (c) a plurality of electrodes (12) positioned at intervals (Figures 1 and 2), including at each terminus (Figure 1), along the trench such as to be in electrical contact with a medium when present in the trench (Figure 3), the plurality of electrodes being connected to activate electrodes to provide an electrical field profile along the trench to move charged particles (implied by col. 9:20-36, which discloses a timing sequence for applying voltages to the electrodes);

placing a sample of the charged particles into the medium in the device (col. 9: 3-10); and
applying a voltage from a voltage source across each adjacent pair of electrodes (col. 9:20-37) such that the electrical field generated across the plurality of electrodes is larger than that achieved in applying a voltage from the voltage source across the electrodes positioned at each terminus of the main trench (implied by “To achieve high resolution separation by molecular charge requires the application of intense electric field gradients, of the order of 250 volts/cm. Rather than apply a large voltage along the entire length of the conduit, much smaller voltages may be applied between more closely spaced but staggered electrodes 122 as seen in

Art Unit: 1753

Fig. 4 and yet maintain high intensity fields.” *col. 9:20-26*).

Pace shows regular intervals for the electrodes. See Figure 4. Even so, Pace discloses that the interval between adjacent electrodes will affect the field gradient produced. See *col. 9:20-22*. Thus, one with ordinary skill in the art at the time of the invention would use irregular or regular intervals depending on the electrical field gradient desired.

11. Claims 39 and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pace (US 4,908,112) (“Pace”) in view of Ramsey (US 6,001,229) (“Ramsey”).

Addressing claim 39, Applicants should note that regarding the limitation “(c) a plurality of branch trenches connected to said main trench for moving charged particles into and out of said main trench” the examiner has only found support back to Application No. 08/615,642, filed March 13, 1996.

Addressing claim 39, Pace discloses a method for moving charged particles through a medium employing an electrical field (*col. 3:52-65*), the method comprising

providing a device comprising (a) a substrate having an upper surface (30), (b) a main trench (32) in the substrate extending downward from the upper surface (Figure 3), and (c) a plurality of electrodes (12) positioned at intervals (Figures 1 and 2), including at each terminus (Figure 1), along the trench such as to be in electrical contact with a medium when present in the trench (Figure 3), the plurality of electrodes being connected to activate electrodes to provide an electrical field profile along the trench to move charged particles (implied by *col. 9:20-36*, which discloses a timing sequence for applying voltages to the electrodes);

placing a sample of the charged particles into the medium in the device (*col. 9: 3-10*); and

applying a voltage from a voltage source across each adjacent pair of electrodes (col. 9:20-37) such that the electrical field generated across the plurality of electrodes is larger than that achieved in applying a voltage from the voltage source across the electrodes positioned at each terminus of the main trench (implied by “To achieve high resolution separation by molecular charge requires the application of intense electric field gradients, of the order of 250 volts/cm. Rather than apply a large voltage along the entire length of the conduit, much smaller voltages may be applied between more closely spaced but staggered electrodes 122 as seen in Fig. 4 and yet maintain high intensity fields.” *col. 9:20-26*)

Pace does not mention providing “a plurality of branch trenches connected to said main trench for moving charged particles into and out of said main trench.” Pace only provides a single branch connected to the main trench for moving charged particles into the main trench. See Figure 1 and col. 6:18. Ramsey a microfluidic device comprising a plurality of branch trenches connected to said main trench for moving charged particles into and out of said main trench. See Figures 1, 8, 14, 20, 16, and 21a-21c. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a plurality of branch trenches as taught by Ramsey in the invention of Pace because then the injection shape of a sample plug can be controlled (col. 5:31-34; col. 6:10-19; and col. 8:9-10) *or* different fluids, such as reagents can be mixed in the main trench (col. 13:3-13, although the discussion is on liquid chromatography, one with ordinary skill in the art would recognize the usefulness to electrophoresis of labeling reactions (see col. 16:16-39)).

Addressing claim 43, for the additional limitation of this claim see col. 5:35-44 in Pace.

Addressing claim 44, Pace does not mention particular intervals for the electrodes. However, Pace does disclose channel dimensions less than 100 microns (col. 5:35-44 and col. 5:60-66) and that the electrodes should be closely spaced to achieve an intense electric field gradient (col. 9:20-22). In light of this disclosure, barring a contrary showing, to have the intervals between the electrodes in the claimed range is just a matter of optimizing the location of the electrodes for the desired field gradient.

Addressing claim 45, Pace shows regular intervals for the electrodes. See Figure 4. Even so, Pace discloses that the interval between adjacent electrodes will affect the field gradient produced. See col. 9:20-22. Thus, one with ordinary skill in the art at the time of the invention would use irregular or regular intervals depending on the electrical field gradient desired.

Addressing claim 46, for the additional limitation of this claim see col. 9:20-33 in Pace.

Information Disclosure Statement

12. Thormann et al. (1981) Analytical Isotachophoresis 33-39, cited on the Information Disclosure Statement of December 10, 2001 was not found in the parent application. Applicants are requested to provide a copy of this article with their response to this Office action.

Art Unit: 1753

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguerola
Primary Examiner
AU 1753
December 22, 2004